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## NOTICE OF ALLOWANCE AND FEE(S) DUE

24239

7590

09/24/2009

MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709 EXAMINER

ALLEN, MARIANNE P

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/24/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569.012	08/11/2006	Javier Dotor De Las Herrerias	020884-000002	8559

TITLE OF INVENTION: PEPTIDES WITH THE CAPACITY TO BIND TO TRANSFORMING GROWTH FACTOR β1 (TGF- β1)

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/24/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correcte maintenance fee notificate	correspondence including below or directed other tions	ng the Patent, advance on nerwise in Block 1, by (a	ders and notification of n a) specifying a new corres	naintenance fees will pondence address; a	I be mailed to the current nd/or (b) indicating a sep	t correspondence address as arate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)  24239  7590  09/24/2009  MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			Fee(	s) Transmittal. This ( rs. Each additional p	certificate cannot be used.	or domestic mailings of the for any other accompanying ent or formal drawing, must
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						(Depositor's name)
			_			(Signature)
			L			(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	Α	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/24/2009
EXAM	INER	ART UNIT	CLASS-SUBCLASS			
ALLEN, MA	ARIANNE P	1647	514-014000			
<ol> <li>Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</li> <li>Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</li> <li>"Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</li> </ol>			2. For printing on the p (1) the names of up to or agents OR, alternativ (2) the name of a single registered attorney or a 2 registered patent attorney or a listed, no name will be	3 registered patent a ely, e firm (having as a m gent) and the names neys or agents. If no	nember a 2	
PLEASE NOTE: Unl recordation as set forti (A) NAME OF ASSIG	less an assignee is ident h in 37 CFR 3.11. Comp GNEE	ified below, no assignee oletion of this form is NO	(B) RESIDENCE: (CITY	ttent. If an assignee tssignment. and STATE OR CO	UNTRY)	document has been filed for
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4a. The following fee(s) are submitted:  ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			<ul> <li>Payment of Fee(s): (Plea</li> <li>A check is enclosed.</li> <li>Payment by credit car</li> <li>The Director is hereby overpayment, to Depo</li> </ul>	d. Form PTO-2038 is authorized to charge	s attached. the required fee(s), any do	
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						he assignee or other party in
Authorized Signature				Date		
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an application. Confident submitting the completed his form and/or suggesti	tiality is governed by 35 d application form to the ions for reducing this but firginia 22313-1450. DC	U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the	1.14. This collection is est depending upon the indiverse Chief Information Office	mated to take 12 mi dual case. Any com r. U.S. Patent and Tr	nutes to complete, includi- ments on the amount of ti ademark Office, U.S. Der	d by the USPTO to process) ng gathering, preparing, and me you require to complete partment of Commerce, P.O. for Patents, P.O. Box 1450,

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24239 7.	590 09/24/2009		EXAM	INER
MOORE & VAN	N ALLEN PLLC	ALLEN, MARIANNE P		
P.O. BOX 13706			ART UNIT	PAPER NUMBER
Research Triangle	Park, NC 27709		1647	
			DATE MAIL ED: 09/24/200	۵

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)				
	10/569,012	DE LAS HERRERIAS ET AL.				
Notice of Allowability	Examiner	Art Unit				
	Marianne P. Allen	1647				
	Iviananne P. Allen	1047				
The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in or other appropriate commu <b>IGHTS.</b> This application is s	this application. If not included unication will be mailed in due course. <b>THIS</b>				
1. $\boxtimes$ This communication is responsive to <u>amendment filed 7/13</u>	<u>3/09</u> .					
2. $\boxtimes$ The allowed claim(s) is/are <u>41-50 herein renumbered as called the second terms of the second term</u>	laims 1-10, respectively.					
3. Acknowledgment is made of a claim for foreign priority up a) All b) Some* c) None of the:  1. Certified copies of the priority documents have		or (f).				
2.  Certified copies of the priority documents have	e been received in Applicatio	n No				
3.   Copies of the certified copies of the priority do	cuments have been received	d in this national stage application from the				
International Bureau (PCT Rule 17.2(a)).						
* Certified copies not received:						
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.						
4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.						
5. CORRECTED DRAWINGS ( as "replacement sheets") must	st be submitted.					
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached						
1)  hereto or 2)  to Paper No./Mail Date						
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date						
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).						
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of In	formal Patent Application				
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)		ummary (PTO-413),				
3. ☐ Information Disclosure Statements (PTO/SB/08),	Paper No./	Mail Date Amendment/Comment				
Paper No./Mail Date						
4.   Examiner's Comment Regarding Requirement for Deposit of Biological Material	8.	Statement of Reasons for Allowance				
/Marianne P. Allen/	9. 🔲 Ottlet	<u>-</u> ·				
Primary Examiner, Art Unit 1647						

#### **DETAILED ACTION**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tristan Anne Fuierer on 9/21/09.

The application has been amended as follows:

Please cancel pending claims 1-4, 6-8, 19, 26, 28-29, and 31-40 without prejudice. Please add new claims 41-50 as set forth below. Basis for these claims is found in at least the original claims and at page 6, lines 21-28.

- 41. (New) A peptide comprising 9, 10, 11, 12, 13, or 14 consecutive amino acids of SEQ ID NO: 17 and their pharmaceutically acceptable salts, wherein the peptide is characterized by a capacity to bind to transforming growth factor  $\beta$ 1 (TGF- $\beta$ 1).
- 42. (New) A peptide comprising an amino acid sequence selected from SEQ ID NO: 17, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:28, SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36, and their pharmaceutically acceptable salts, wherein the peptide is characterized by a capacity to bind to transforming growth factor β1 (TGF-β1).
- 43. (New) The peptide according to claim 41 comprising SEQ ID NO: 17.

Art Unit: 1647

- 44. (New) The peptide according to claim 41 comprising SEQ ID NO: 33.
- 45. (New) The peptide according to claim 41 comprising SEQ ID NO: 34.
- 46. (New) The peptide according to claim 41 comprising SEQ ID NO: 35.
- 47. (New) The peptide according to claim 41 comprising SEQ ID NO: 36.
- 48. (New) The peptide according to claim 41 or 42 characterized in that the peptide has the capacity to inhibit the biological activity of TGF-β1 *in vitro* and/or *in vivo*.
- 49. (New) A method of making a pharmaceutical composition, said method comprising introducing the peptide of claim 41 or 42 into a pharmaceutically acceptable excipient.
- 50. (New) A pharmaceutical composition comprising the peptide of claim 41 or 42 and at least one pharmaceutically acceptable excipient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/ Primary Examiner, Art Unit 1647

mpa